



"EXPRESS MAIL CERTIFICATE"
"EXPRESS MAIL" MAILING LABEL NUMBER EV332944755US
DATE OF DEPOSIT November 10, 2003

Attorney Docket No. P31828C3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stephen Alistair Smith November 10, 2003
Serial No.: Not Yet Assigned Group Art Unit No.: Not Yet Assigned
Filed: Herewith Examiner: Not Yet Assigned
For: TREATMENT OF DIABETES WITH THIAZOLIDINEDIONE AND
SULPHONYLUREA

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FILING OF AN INFORMATION DISCLOSURE STATEMENT UNDER
37 C.F.R. §1.97(b)

The attached list of citations on PTO Form 1449 is being submitted under the provisions of 37 CFR §1.56 and §1.97 in order to comply with the duty of disclosure. Their inclusion herein should not, however, be construed as an admission that any particular cited reference is effective prior art or that it discloses or renders obvious any aspect of the claimed invention. A copy of each cited reference is enclosed, except for those references which are already part of the filewrapper. This statement is being filed within the time period specified in 37 CFR §1.97(b). No fee is required.

Respectfully submitted,

Kathryn L. Sieburth
Attorney for Applicants
Registration No. 40,072

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5012
Facsimile (610) 270-5090
N:\kls\cases\p31828c3\IDS Letter.doc

| | | | |
|--|--|-------------------------------------|--------------------------------|
| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | ATTY. DOCKET NO. P31828C3 | SERIAL NO. Not Yet Assigned |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | | APPLICANT Stephen Alistair Smith | |
| | | FILING DATE Herewith | GROUP Not Yet Assigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|---------------------|--|--------------------|------|------|-------|----------|-------------------------------|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation | |
|--|--|--------------------|------|---------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|---|--|
| | Avandia Drug Profile. <i>PDR Health Website</i> – www.pdrhealth.com |
| | Weinstock, et al. <i>Int'l. J. Exp. Clin. Pharmacol.</i> , <u>54</u> : 169-178 (1997). |
| | Iwamoto, et al., "Effect of Combination Therapy of Troglitazone and Sulphonylureas in Patients with Type 2 Diabetes Who Were Poorly Controlled By Sulphonylurea Therapy Alone". <i>Diabetic Medicine</i> , <u>13</u> : 365-370 (1995). |
| | Alberti, et al., "A Desktop Guide for the Management of Non-Insulin Dependent Diabetes Mellitus (NIDDM): An Update". <i>Diabetic Medicine</i> , <u>11</u> : 899-909 (1994). |
| | Iwamoto. "Usage of New Oral Anti-Diabetic Drugs". <i>Klinika</i> , <u>22(6)</u> pp. 445-450 (1995). |
| | Nakano, et al., "Clinical Evaluation of a New Oral Hypoglycemic Drug, CS-045, on Daily Profile of Blood Glucose in Patients with Non-Insulin Dependent Diabetes Mellitus". <i>Rinsyou Iyaku (Clinical Medicine)</i> , <u>9th Vol., Supp. 3</u> : pp. 151-164 (1993). |
| | |
| | |
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|-------------------------------------|--------------------------------|
| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | ATTY. DOCKET NO. P31828C3 | PRED. SERIAL NO. 10/103,326 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | | APPLICANT Stephen Alistair Smith | |
| | | PRED. FILING DATE March 21, 2002 | GROUP Not Yet Assigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------------|----------|--------------------|-------|----------|----------------------------|
| | 5,965,584 | 10/1999 | Ikeda, et al. | 514 | 342 | |
| | US20020016287 | 2/7/02 | Buckingham, et al. | 514 | 3 | |
| | US20020177612 | 11/28/02 | Grannett, et al. | 514 | 340 | |
| | 6,291,495 | 9/18/01 | Rieveley | 514 | 369 | |
| | 6,153,632 | 11/28/00 | Rieveley | 514 | 369 | |
| | 5,972,973 | 10/26/99 | Whitcomb | 514 | 342 | |
| | 5,859,037 | 1/12/99 | Whitcomb | 514 | 369 | |
| | 5,952,356 | 9/14/99 | Ikeda, et al. | 514 | 340 | |
| | 6,150,383 | 11/21/00 | Ikeda, et al. | 514 | 342 | |
| | 6,031,004 | 2/29/00 | Timmins, et al. | 514 | 635 | |
| | 4,985,862 | 1/23/90 | Alessi, et al. | 514 | 360 | |
| | 5,068,342 | 11/26/91 | Zask, et al. | 548 | 183 | |

FOREIGN PATENT DOCUMENTS

| | Document Number | Date | Country | Class | Subclass | Translation | |
|--|-----------------|---------|---------|-------|----------|-------------|----|
| | | | | | | Yes | No |
| | WO 98/36755 | 8/1998 | PCT | | | | |
| | 0 861 666 | 9/1998 | EPO | | | | |
| | WO 93/03724 | 3/1993 | PCT | | | | |
| | 0 749 751 | 12/1996 | EPO | | | | |
| | 0 306 228 | 3/1989 | EPO | | | | |
| | WO 99/03478 | 1/28/99 | PCT | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|--|---|
| | Kelley, et al., "Troglitazone", <i>Current Opinion in Endocrinology and Diabetes</i> , <u>5(2)</u> : 90-96 (1998) (XP002080820). |
| | Scheen, et al., "Oral Antidiabetic Agents, A Guide to Selection", <i>Disease Management</i> , <u>55(2)</u> : 225-236 (XP002080821). |
| | Scheen et al., "Drug Treatment of Non-Insulin-Dependent Diabetes Mellitus in the 1990s. Achievements and Future Developments". <i>Drugs</i> , <u>54(3)</u> : 355-368 (1997) (XP002080822). |
| | Iwatamoto, et al., "Effect of Combination Therapy of Troglitazone and Sulphonylureas in Patients with Type 2 Diabetes Who Were Poorly Controlled by Sulphonylurea Therapy Alone". <i>Diabetic Medicine</i> , <u>13(4)</u> : 365-370 (1996) (XP002064289). |
| | Gareth Williams. "Management of Non-Insulin-Dependent Diabetes Mellitus", <i>The Lancet</i> , <u>343</u> : 95-100 (1994). |
| | Kuzuya, et al., "A Pilot Clinical Trial of a New Oral Hypoglycemic Agent, CS-045, in Patients with Non-Insulin Dependent Diabetes Mellitus". <i>Diabetes Research & Clinical Practice</i> , <u>11</u> : 147-154 (1991). |
| | Lehmann, et al., "An Antidiabetic Thiazolidinedione is a High Affinity Ligand for Peroxisome Proliferator-Activated Receptor γ (PPAR γ)". <i>J. Biol. Chem.</i> , <u>270(22)</u> : 12953-12956 (1995). |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | |
|--|--|-------------------------------------|--------------------------------|
| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | ATTY. DOCKET NO. P31828C3 | PRED. SERIAL NO. 10/103,326 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | | APPLICANT Stephen Alistair Smith | |
| | | PRED. FILING DATE March 21, 2002 | GROUP Not Yet Assigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------------|--------|---------------------|-------|----------|----------------------------|
| | 5,900,435 | 5/4/99 | Martin D. Meglasson | 514 | 565 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

FOREIGN PATENT DOCUMENTS

| | Document Number | Date | Country | Class | Subclass | Translation | |
|--|-----------------|---------|---------|-------|----------|-------------|----|
| | | | | | | Yes | No |
| | WO 97/17975 | 5/22/97 | PCT | | | | |
| | WO 95/21608 | 8/1995 | PCT | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|--|--|
| | Donnelly, et al., "Drugs and Insulin Resistance: Clinical Methods of Evaluation and new Pharmacological Approaches to Metabolism". <i>Br. J. Clin. Pharmacol.</i> , <u>37</u> : 311-320 (1994). |
| | Jackson, et al., "Mechanism of Metformin Action in Non-Insulin-Dependent Diabetes". <i>Diabetes</i> , <u>36</u> : 632-640 (1987). |
| | Hofmann, et al., "New Oral Thiazolidinedione Antidiabetic Agents Act as Insulin Sensitizers". <i>Diabetes Care</i> , <u>15</u> (8): 1075-1078 (1992). |
| | Foot, et al., "Improved Metabolic Control by Addition of Troglitazone to Glibenclamide Therapy in Non-Insulin Dependent Diabetics". <i>Diabetologia</i> , <u>38</u> (S1): A44 (1995). |
| | Whitcomb, et al., "Thiazolidinediones". <i>Exp. Opin. Invest. Drugs</i> , <u>4</u> (12): 1299-1309 (1995). |
| | Leif C. Groop, "Sulfonylureas in NIDDM". <i>Diabetes Care</i> , <u>15</u> (6): 737-754 (1992). |
| | Vialettes, et al., "Pharmacological Approach in the Treatment of Insulin Resistance". <i>Horm. Res.</i> , <u>38</u> : 51-56 (1992). |
| | Sohda, et al., "Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl]thiazolidine-2,4-dione (ADD-3878) and its Derivatives". <i>Chem. Pharm. Bull.</i> , <u>30</u> (10): 3580-3600 (1982). |
| | Harold E. Lebovitz, "Stepwise and Combination Drug Therapy for the Treatment of NIDDM". <i>Diabetes Care</i> , <u>17</u> (12): 1542-1544 (1994). |
| | Iwamoto, et al., "effect of New Oral Antidiabetic Agent CS-045 on Glucose Tolerance and Insulin Secretion in Patients with NIDDM". <i>Diabetes Care</i> , <u>14</u> (11): 1083-1086 (1991). |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | | |
|--|--|-------------------------------------|--------------------------------|
| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | ATTY. DOCKET NO. P31828C3 | PRED. SERIAL NO. 10/103,326 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | | APPLICANT Stephen Alistair Smith | |
| | | PRED. FILING DATE March 21, 2002 | GROUP Not Yet Assigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|---------------------|--------------------|------|------|-------|----------|-------------------------------|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

FOREIGN PATENT DOCUMENTS

| | Document Number | Date | Country | Class | Subclass | Translation | |
|--|--------------------|------|---------|-------|----------|-------------|----|
| | | | | | | Yes | No |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|---|---|
| | Hotta. <i>Tonyobyu</i> , <u>Update 10</u> , pp. 68-77, April 1994 (with translation). |
| | Hotta. <i>Chronic Disease</i> , <u>6(1)</u> . January 5, 1995. |
| | Ishida, et al., "Oral Hypoglycemic Agents – New Oral Drugs and New Strategy of Treatment". <i>Clinic All-Round</i> , <u>43</u> : 2615-2621 (1994). |
| | Cusi, et al., "Metformin: A Review of its Metabolic Effects". <i>Diabetes Review</i> , <u>6(2)</u> : 89-131 (1998). |
| | Arshag D. Mooradian. "Drug Therapy of Non-Insulin-Dependent Diabetes Mellitus in the Elderly". <i>Drugs</i> , <u>51(6)</u> : 931-941 (1996). |
| | Windholz, et al., <i>The Merck Index</i> , 10th Edition, pp. 635. Abstract Nos. 4300 & 4302 (1983). |
| | K. Doi, "New Oral Hypoglycemic Agents and Hypoglycemic Agents Under Development". <i>J. Japan Diabetes Science</i> , <u>3(Supp. 1)</u> : 962-973 (1990). |
| | Kramer, et al., "Differential Interaction of Glimepiride and Glibenclamide with the Beta-Cell Sulfonylurea Receptor 2 Photoaffinity-Labeling of a 65 KDA Protein by H-3 Glimepiride. <i>Biochim. et Biophys. Acta-Biomembranes</i> , <u>1191(2)</u> : 270-290 (1994). |
| | |
| | |
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |